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Transrectal high-intensity focused ultrasound (HIFU) treatment of localized prostate cancer: Review of technical incidents and morbidity after 5 years of use

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ABSTRACT

OBJECTIVE

To report on technical incidents, and early and late complications, occurring on high-intensity focused ultrasound (HIFU) treatment of patients with localized prostate cancer.

PATIENTS AND METHODS

We performed a retrospective review of patients who were treated by Ablatherm™ in our centre. We recorded all technical incidents, treatment discontinuations, and early (< 1 month) and late complications.

RESULTS

A total of 74 HIFU procedures were performed in 65 patients (55 first-line HIFU treatments, 10 cases of salvage therapy after radiotherapy) over a 5-year period. Median follow-up was 41 months (10-64). All the procedures were well tolerated and no intra-operative or peri-operative deaths occurred. Six technical incidents in the overall population (8.1%) led to discontinuation of the procedure. The early complication rate in patients undergoing first-line HIFU was 36.4%: urinary retention (20%), dysuria (5.4%), urinary infection (3.6%), haematuria (3.6%), and urethral stenosis (3.6%). The late complication rate was 12.7%: urethral stenosis (9%) and dysuria (3.6%). There were no cases of rectourethral fistula. The long-term urinary incontinence rate was 20% and the *de novo* erectile dysfunction rate was 77.1%. Nine complications (16.4%) required surgical management. The overall complication rate was 49%.

CONCLUSIONS

Ablatherm™ is a reliable technique with a relatively high complication rate. However, most complications were minor and required surgical management in a few cases only. Our results confirm that all patients offered HIFU treatment should be properly informed of the risks, in particular with regard to continence and sexual function.

KEYWORDS: Localized prostate cancer, minimally invasive therapy, high-intensity focused ultrasound, HIFU, side effects, technical incidents

INTRODUCTION

High-intensity focused ultrasound (HIFU) is an emerging technology for the treatment of localized prostate cancer. Its efficacy and safety have been demonstrated in several studies [1,2]. It is considered to provide a level of local control (i.e. negative biopsy rate) similar to that of other treatment options [3]. Its advantages are manifold according to the investigator centres: it is minimally invasive, it can be repeated if required, and other treatments can be offered in cases of incomplete treatment or recurrence [4,5]. Currently, it is used in patients who are not eligible for surgery or as salvage therapy for local recurrence after radiotherapy. Patients are often informed that the treatment is local and precise, can be repeated, requires a short hospital stay and is associated with few side-effects. However, relatively few studies have addressed the complications of HIFU and, to our knowledge, none has described the technical problems that may be encountered. Recently, a British team decided to suspend their HIFU treatment programme because of significant rates of oncological failure and complications [6].

The aim of this retrospective study was to review the technical incidents and the complications encountered by a non-investigator centre in the use of the HIFU procedure in the treatment of localized prostate cancer.

PATIENTS AND METHODS

The files of all patients who underwent HIFU treatment for localized prostate cancer in our centre between April 2004 and November 2008 were reviewed. All HIFU procedures had been performed by two practitioners trained in the technique at the investigator centre where the technique originated (Edouard Herriot Hospital, Lyon, France). The first 4 procedures were performed under the supervision of Professor Albert Gelet, MD, PhD.

A second generation Ablatherm™ device was used. After March 2005, this was a robot-assisted Ablatherm™ device with Real Time Integrated Imaging. Transurethral resection of the prostate (TURP), when performed, was carried out during the 3 months before the HIFU procedure and not concomitantly with the procedure. HIFU treatment was performed under general anaesthesia. After insertion of a 18 F Foley catheter for bladder drainage, the patient

was transferred to the Ablatherm™ platform and placed in the right lateral position. The ultrasound probe was positioned in the rectum. The volume to be treated was defined by the urologist using the longitudinal and transverse ultrasound imaging system. Treatment was delivered in 4 to 6 treatment blocks depending upon gland size, and was initiated 6 mm from the apex to protect the external sphincter. Lesion size had a constant diameter of 1.7 mm but could be modified in length from 19 to 24 mm. Each shot lasted 5 sec and was followed by a 5-sec interval, for a first HIFU treatment. The central prostate zone was treated separately from the lateral zones and, during treatment of midline blocks containing the urethra, the catheter was removed. It was reinserted upon procedure completion and usually remained in place for 72 hours. Patients were discharged the day after catheter removal. No nerve-sparing surgery was performed and no systematic antibiotic treatment was given before, during or after the HIFU procedure.

The indications for HIFU treatment complied with French Urology Association guidelines: stage T1-T2b tumours, prostate specific antigen (PSA) ≤ 15 ng/ml, <4 positive biopsies, and a Gleason score of ≤ 7 in patients who did not qualify for or refused surgery. Account was taken of life expectancy. Treatment was reserved for prostates smaller than 50 cc in order to limit treatment time and need for a second session [7,8].

Data were collected on technical incidents, procedure discontinuations regardless of technical cause, and consequences. Early complications were defined as all complications occurring during the month following the procedure, and late complications as those occurring after 1 month. Stress incontinence was graded as described by Ingelman-Sundberg [9]. Sexual function before and after HIFU treatment was assessed by posing a set of short questions exploring erectile function, sexual activity, and ability to have sexual intercourse (non-validated questionnaire). Postoperative erectile dysfunction (ED) was defined as the *de novo* inability to have sexual intercourse without pharmacological assistance. Follow-up monitoring included a digital rectal examination and PSA test. Visits took place at 1 month, then every 3 months for the first year, and every 6 months thereafter.

RESULTS

A total of 74 HIFU procedures were performed in 65 patients treated for a prostate adenocarcinoma. Prostate cancer treatment by HIFU was first-line in 55 patients and second-line (salvage therapy for local recurrence after external beam radiotherapy) in 10 patients. The mean age of the 55 patients was 72 ± 4.8 years. Clinical stage was T1 in 38 patients (69.1%) and T2 in 17 patients (30.9%). Five patients (13.1%) had T1a disease and 6 (15.8%) had T1b disease. Median pre-treatment PSA was 7 ng/ml (range: 0.29-13.4). Patient stratification according to Gleason grade was as follows: <6 (10.9%), 6 (67.3%), and 7 (21.8%). The median size of prostates treated (after TURP and prior to HIFU) was 18 cc (± 8.6). On average, 138% of the overall median gland volume was treated after a HIFU session. Median follow-up was 41 months [10-64].

Forty-nine patients (89.1%) had undergone preoperative TURP. Of these, 37 underwent TURP during the 3 months before the HIFU procedure (mean, 1.75 ± 0.76 months) and 12 had undergone TURP much earlier (mean, 10.7 ± 8.9 months) for the treatment of prostatic symptoms. The mean weight of resected tissue in the two groups was 14.9 g (range, 1-74 g) and 32.5 g (range, 10-114 g), respectively. Of the 12 “early TURP” patients, 3 (25%) had T1a disease and 5 (41.6%) had T1b disease. None required further resection during the 3 months before HIFU treatment. TURP was not performed in 6 patients with a very low prostatic volume (<15 cc) and no prostatic symptoms. All patients were continent before the HIFU procedure.

All the procedures were well tolerated and no intra-operative or peri-operative medical complications or deaths occurred. Six technical incidents occurred during the 74 HIFU sessions (8.1% rate). A telephone help-line did not enable resolution of these incidents which, in each case, led to treatment discontinuation. Only one of the 6 patients required a repeat session, at 3 months, because of a persistently high PSA level. The other 5 patients underwent close clinical surveillance and biochemical monitoring. Treatment was also discontinued in 6 other cases (8). Table 1 summarizes results by type of 2nd generation Ablatherm™ device

(early device or robot-assisted device with integrated imaging) and by treatment (first-line or salvage).

Complication rate was calculated for the 55 patients who underwent first-line HIFU treatment for prostate cancer (46/55: 1 session; 9/55: 2 sessions). The 10 patients with localized prostate cancer who had undergone previous radiotherapy were excluded from the calculation to avoid bias [10,11]. Fifteen patients (36.4%) experienced 20 early complications and 7 patients (12.7%) experienced 7 late complications. Overall, 27 treatment-related side effects were reported in 55 patients (49%). Complications are summarized in Table 2. One case of urinary retention was encountered in a patient who did not undergo TURP. There were no cases of rectourethral fistula or of chronic perineal pain syndrome.

Early and late functional outcomes (continence and erectile function) are given in Table 3. There were 6 cases of early stress incontinence (10.9%) and 11 of late stress incontinence (20%). The patient with late grade III stress incontinence underwent placement of a suburethral sling. Overall, 9 complications (16.4%) required surgical management (Table 2). Data on pre- and postoperative erectile function were available for 51 patients (92.7%). There were 27 cases (77.1%) of *de novo* ED. Eight patients (29.6%) received long-term ED treatment, either type 5 phosphodiesterase inhibitor (n =7) or intracavernous injections (n = 1). Table 4 summarizes early and late complications and functional outcomes according to type of Ablatherm™ device.

Among the 10 patients who benefited from salvage HIFU after radiotherapy, one patient experienced early acute prostatitis; another experienced late dysuria and was treated by necrosectomy. No patient undergoing salvage therapy presented urinary incontinence.

DISCUSSION

The technical incidents rate in our study was 8.1% for a total of 74 HIFU procedures. All 6 incidents led to treatment discontinuation but only one patient required a second HIFU session because of a persistently high PSA level 3 months after the interrupted procedure. A single technical incident was reported during the 14 sessions using the pre-2005 Ablatherm™ device with no integrated imaging, highlighting the reliability of the early device. Treatment

was also discontinued in a further 8% of patients because of either ultrasound detection problems (2 cases) or an excessive rectal wall thickness (4 cases).

One patient with excessive rectal wall thickness was a case of salvage therapy after radiotherapy. Radiotherapy can increase rectal wall thickness, making prostate contours more difficult to detect. However, thanks to the technical innovations brought to the earlier Ablatherm™ device, a better match can now be obtained between the target zone and the prostate capsule contour. New adjustments, such as variable lesion height and safety features protecting the rectum, mean that more patients with local relapse after external beam radiotherapy may now undergo HIFU treatment. The ease of the procedure has increased for the operator. In our 10 patients, salvage therapy was not associated with a greater number of technical difficulties but this result needs to be confirmed in larger studies.

Like Poissonnier et al., we encountered no cases of rectourethral fistula [3]. Thüroff et al. reported a 1.2% incidence rate [1]. Fistulas may be due to impairment of the rectal wall by cavitation and temperature elevation [12]. Five cases of rectal fistula have been reported in patients who had previously undergone brachytherapy and/or radiotherapy [5,13]. Rectal fistulas can be prevented by monitoring rectal wall thickness (<6 mm), better knowledge of heat diffusion, and better real-time control of the HIFU shots and of the cooling system [1]. Treatment parameters need to be adapted in cases of hypovascularized irradiated tissue as such tissue conducts less heat and generates higher temperatures. The recommendation is to decrease shot duration to 4 sec and increase shot interval to 7 sec. Currently, the risk of rectourethral fistulas is close to zero [3,14].

The most common complication of the HIFU procedure is urinary retention due to an increase in prostate volume and/or the passage of necrotic debris. Our urinary retention rate was higher (20%) than reported rates (0.3% and 8.6% [1,15]) but we observed no urinary retention after the first postoperative month. Our higher retention rate may be due to a short bladder drainage time of 72 hours although short times appear to be feasible if TURP precedes treatment [16]. In our study, 49 patients (89.1%) underwent TURP before the HIFU procedure.

The aim of TURP is to reduce the risk of prolonged HIFU-related urinary retention. Unlike Vallancien et al. and Chaussy et al., we performed TURP before and not concomitantly with HIFU [16,17]. Vallancien et al. concluded in a non-comparative study that the combination of

endoscopic resection or incision of the prostate with HIFU treatment decreased urinary catheterization time and improved post-treatment urinary status without additional morbidity [17]. Chaussy and Thüroff, who compared the treatment-related morbidity of combined TURP-HIFU treatment and HIFU alone, concluded that the combined treatment significantly reduced morbidity and that patient management did not differ to that after just TURP [16]. Catheter time, incontinence, urinary infection and post-treatment International Prostate Symptom Score (I-PSS) were significantly reduced. In addition, there was less need to resort to additional deobstruction procedures (necrosectomy, urethrotomy) which may cause incontinence.

However, the addition of TURP to HIFU may predispose the patient to an increased incidence of stricture and/or stress incontinence. Bladder neck resection during TURP and disruption of the bladder neck continence mechanism may cause incontinence. However, the primary continence mechanism post-TURP is the intrinsic urethral sphincter which is also the primary determining factor for continence preservation post-HIFU. We performed TURP on average 1.75 months before the HIFU procedure and observed no urinary incontinence before the procedure. However, larger studies would be needed to confirm that there is no difference between a population of patients with an intact bladder neck and a population undergoing combined treatment. A shorter catheter time with TURP may be at the expense of a higher risk of incontinence.

According to a recent study, bladder outlet obstruction after HIFU seems to be associated with older age, and TURP before HIFU was apparently not an independent factor in preventing obstruction [18]. However, multiple episodes of bladder outlet obstruction could be reduced by resecting more tissue at TURP before HIFU [18]. The necrosectomy rate for urinary retention or dysuria was lower in our study than in Blana et al.'s (7.2% vs 11.7%) [19].

There were 7 cases of urethral stenosis (12.6%) of which 4 were managed by internal urethrotomy. Published rates for post-HIFU stenosis range from 3.6% to 22% [1,20]. A recent study with a mean follow-up of 6.4 years gave a 13.6% rate [14]. Our urinary infection rate was 3.6%. It was lower than the 7.8% rate reported in a 8-year study of 163 patients [2] and than the 16% rate in a study patients with high-risk prostate cancers [21]. Infection responded

to appropriate antibiotic treatment. Combined HIFU plus TURP treatment has been shown to be associated with a lower infection rate than HIFU alone (11.4% vs 47.9%) [16].

The stress incontinence rate in our patients was 20% (12.7% for grade I) and was higher than previously reported. Grade I and II incontinence rates of 6.1% and 1.8%, respectively, have been reported after 8 years of follow-up [2], and rates of 5% and 0.7% after a median of 6.4 years of follow-up [14]. Better identification of the prostate apex and leaving a 4-6 mm treatment margin at the apex have reduced the risk of incontinence [22]. None of our 10 patients in the salvage group presented incontinence but their risk of incontinence was higher. Murat et al. reported an incontinence rate of 49.5% in salvage patients, which included a 31.5% rate of grade 2 or 3 incontinence [10]. Currently, improvements in imaging and specific post-radiation treatment parameters have reduced this risk [10].

The *de novo* postoperative ED rate in our study was 77.1% compared to rates of 20% and 77% in recent studies [23,24]. We prescribed postoperative ED therapy to a higher proportion of patients (n=8, 29.6%) than another study did (20%) [25]. However, our study was not a review of a prospectively maintained database, the population size was relatively small, and we did not use a validated potency questionnaire. Moreover, our centre does not perform nerve-sparing HIFU because of the oncological risk and the likelihood of repeat treatment [3,26,27]. Repeat HIFU carries a significantly higher risk of impotency and incontinence [28]. Specific criteria have been established for repeat treatment because of the lesions occurring after a first procedure [29,30] and the problems in detecting prostate boundaries for a repeat procedure.

Our results, albeit in a limited series of patients, thus do not support the early claims of low morbidity and good functional outcomes in patients undergoing HIFU treatment for localized prostate cancer [1]. Our overall complications rate of 49%, including a 20% rate of late stress incontinence and a 77.1% *de novo* ED rate was relatively high. However, this emerging technology is not a morbid procedure but rather a procedure that is not completely complication free. It is less invasive than conventional therapies such as radical prostatectomy, radiotherapy, or brachytherapy. It does not require an incision or puncture, is bloodless, deliverable on an outpatient basis, safe, and repeatable, with a fairly rapid recovery time. The 2009 European Association of Urology guidelines still consider it “investigational

or experimental” [31]. Technological advances will hopefully improve the morbidity rates which will need to be assessed in well-designed trials with longer follow-ups.

In our study, we used the Ablatherm™ rather than Sonablate500™ device. The complication rates of these two devices have been compared in a head-to-head, but non randomized, comparison which revealed no significant differences in morbidity [32].

In conclusion, the Ablatherm™-HIFU procedure seems fairly reliable with a technical incidents rate of 8.1%. The overall complication rate was high (49%) over a median follow-up of 41 months. Most complications were minor, requiring surgical management in 16.4% of cases. Our results confirm that all patients offered HIFU treatment should be properly informed of the risks, in particular with regard to continence and sexual function.

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Table 1. Technical incidents and treatment discontinuations by type of device and treatment group

Type of 2 nd generation Ablatherm™ HIFU device	Treatment	Procedures (N)	Technical incidents n (%)	Treatment discontinuations n (%)
Early device (Apr. 2004 – Mar. 2005)	First-line	13	Computer incident 1 (7.7)	Excessive rectal wall thickness - 1 (7.7)
	Salvage	1	0	0
Robot-assisted with real time integrated imaging (Mar. 2005 – Nov. 2008)	First-line	51	Probe blockage - 2 (3.9) Abnormal cooling fluid temperature - 2 (3.9) Computer incident - 1 (1.9)	Excessive rectal wall thickness - 2 (3.9) Ultrasound detection problems - 2 (3.9)
	Salvage	9	0	Excessive rectal wall thickness - 1 (11.1)

TABLE 2. Complication rates after HIFU treatment (N= 55)

Complications and treatment	Urinary retention N (%)	Dysuria N (%)	Acute prostatitis N (%)	Urethral stenosis N (%)	Haematuria N (%)
Early (<1 mo)	11 (20)	3 (5.4)	2 (3.6)	2 (3.6)	2 (3.6)
Treatment	Bladder catheter (9) Necrosectomy (2)	-	Antibiotics (2)	Internal urethrotomy (2)	Bladder washing (2)
Late (>1 mo)	0	2 (3.6)	0	5 (9.0)	0
Treatment	-	Necrosectomy (2)	-	Internal urethrotomy (2) Autodilatation (1)	-
Total	11 (20)	5 (9.0)	2 (3.6)	7 (12.6)	2 (3.6)

Urinary retention: Lack of ability to urinate with a full bladder

Dysuria: Difficult, sometimes painful urination, often characterized by straining

TABLE 3. Functional outcomes

	Preoperative N (%)	Postoperative N (%)	
		< 1 month	> 1 month
Stress incontinence (N =55) *			
Grade I	0	4 (7.3)	7 (12.7)
Grade II	0	2 (3.6)	3 (5.4)
Grade III	0	0 (0)	1 (1.8)
Erections (N = 51)	35 (68.6)	8 (15.7)	
Sexual activity (N = 51)	24 (47)	2 (3.9)	

* graded as described by Ingelman-Sundberg [9].

Table 4. Complications and functional outcomes according to device

Type of 2 nd generation Ablatherm™ HIFU device	Urinary retention N (%)	Dysuria N (%)		Acute prostatitis N (%)	Urethral stenosis N (%)		Haematuria N (%)	Stress incontinence N (%) N + Grade I,II,III		ED N
		Early	Late		Early	Late		Early	Late	
Early device (Apr. 2004 – Mar. 2005) (N=12)	4 (33) <i>1 necro- sectomy</i>	0	0	0	0	2 (16.6) <i>1 IU</i>	0	1 (8.3) <i>1II</i>	3 (25) <i>1I, 2II</i>	2
Robot-assisted with real time integrated imaging (Mar. 2005 – Nov. 2008) (N=48)	7 (16.3) <i>1 necro- sectomy</i>	3 (6.9)	2 (4.6)	2 (4.6)	2 (4.6) <i>2 IU</i>	3 (6.9) <i>1 IU</i>	2 (4.6)	5 (11.6) <i>4I, 1II</i>	8 (18.6) <i>6I, 1II,1III</i>	25

ED: Erectile dysfunction; IU: Internal urethrotomy